Endovascular Femoropopliteal Bypass: Early Human Cadaver and Animal Studies

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We report herein a feasibility study of a minimally invasive endovascular femoropopliteal bypass procedure. The steps include the following: (1) a small groin incision to expose the femoral artery, (2) guidewire passage and mechanical dilatation of the diseased superficial femoral artery, (3) semiclosed endarterectomy of the superficial femoral artery using an expandable metal endarterectomy catheter that engages atheroma, (4) placement of a 6 mm thin-walled PTFE graft, (5) balloon dilatation of the graft to press the graft flat against the arterial wall, and (6) a standard end-to-end anastomosis of the proximal graft to the femoral artery. This technique was tested in 13 limbs from eight fresh (stored 1 to 5 days at 4° C) human cadavers (seven females and one male). Five limbs had stenotic superficial femoral artery lesions, 1 to 15 cm (mean 7.6 cm). Four limbs had occlusive lesions, 9 to 38 cm long (mean 26.8 cm). Four limbs had no disease. We successfully completed the procedure in 10 of 13 limbs. Completion arteriography showed a widely patent graft and a popliteal artery with a smooth distal graft/arterial interface in 9 of 10 limbs; one had a distal graft fold due to a size mismatch. Histologic studies of the superficial femoral artery revealed intima, atheromatous plaque, and media. We failed to complete our procedure in three limbs: two because of inadequate instruments and one because of perforation of the artery. We also performed the same procedure unilaterally in six dogs, except that no endarterectomy was performed. Each dog was an adult male of Greyhound or Labrador descent that weighed 32 to 86 kg (mean 49 kg). We achieved technical success in all six dogs and arteriographic success in four of six dogs. In two dogs completion arteriography revealed a longitudinal fold near the distal end of the graft that was attributed to a size mismatch. We conclude that endovascular femoropopliteal bypass is feasible and warrants further studies for possible clinical application. (Ann Vasc Surg 1995;9:28-36.)

Femoropopliteal bypass remains the gold standard for the treatment of superficial femoral artery occlusive disease.[1,2] Endovascular procedures such as balloon angioplasty and atherectomy are less invasive but also less effective.[3,4] Endarterectomy has patency results similar to those of bypass but is more difficult to perform and sometimes more invasive.[5,6] We postulated that an endovascular femoropopliteal bypass could offer the durability of a standard femoropopliteal bypass and the benefit of a less invasive endovascular procedure. To accomplish this we proposed performing a semiclosed endarterectomy and placing a synthetic graft in the femoropopliteal position through a single small groin incision.

The purpose of this study was to evaluate the feasibility of such a procedure. We describe herein our early experience in fresh human cadavers and live animals. Specifically we address the technical

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Table I. Cadaver summaries

Cadaver	Age (yr)	Sex	Body habitus	Fem-Pop disease	Disease length (cm)
1	99	F	Cachectic	L occlusion	9
				R occlusion	38
2	85	F	Normal	L occlusion	30
				R occlusion	30
3	93	F	Cachectic	R multiple-stenoses	14
4	80	F	Normal	L stenosis	1
				R stenosis	1
5	96	F	Cachectic	L stenosis	8
				R stenosis	14
6	84	F	Obese	L None	N/A
7	84	F	Normal	R None	N/A
8	64	M	Obese	L None	N/A
				R None	N/A

N/A = not applicable.

aspects of endarterectomy, graft placement, and graft fixation. Studies to determine the efficacy and durability of endovascular femoropopliteal bypass are still in progress.

MATERIAL AND METHODS

Human Cadaver Studies

We obtained eight cadavers (seven female and one male) that met the following criteria: age >60 years, death within 5 days, and a history of arteriosclerotic disease. In these eight cadavers we performed endovascular femoropopliteal bypass in 13 limbs. Three of these limbs were not used because of unavailability of the fluoroscopy room. The characteristics of these cadavers and their arteriosclerotic disease are listed in Table I.

These cadavers underwent endovascular femoropopliteal bypass as follows:

1. Cut down and exposure of the common femoral, superficial femoral, and profundofemoral arteries (Fig. 1)
2. Transverse fishmouth arteriotomy of the superficial femoral artery (Fig. 2, *A*)
3. Insertion of an introducer sheath and passage of the guidewire across the lesion distally (Fig. 2, *B*)
4. Mechanical dilatation of the diseased superficial femoral artery using a bullet-shaped 12 and 15 F metal dilator that rotates at 400 rpm (Dynamic Dilator, EndoVascular Instruments, Inc., Portland, Ore.) (Fig. 3, *A*)
5. Semiclosed endarterectomy using an expandable metal endarterectomy catheter that engages atheroma and allows transluminal extraction of plaque (Endarterectomy Catheter, EndoVascular Instruments, Inc.) (Fig. 3, *B*)

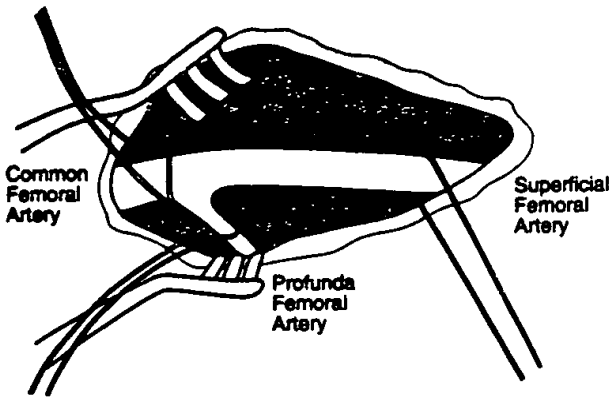

Fig. 1. Exposure of the common femoral, superficial femoral, and profunda femoral arteries.

6. Placement of an 18 F peel-away introducer sheath (Fig. 4, *A*)
7. Placement of a 6 mm thin-walled PTFE graft through the introducer sheath and into the femoropopliteal position with the distal graft 1 cm beyond the endarterectomy end point (Fig. 4, *B*)
8. Removal of the peel-away sheath while holding the PTFE graft in place using a graft inserter (Graft Inserter, EndoVascular Instruments, Inc.) (Fig. 5, *A*)
9. Removal of the Graft Inserter
10. Balloon dilatation of the graft to press the graft flat against the arterial wall using a standard 6 mm percutaneous transluminal angioplasty balloon (C.R. Bard, Inc., Billerica, Mass., or Olbert Catheter System, Meadox Surgimed, Stenløse, Denmark) (Fig. 5, *B*)

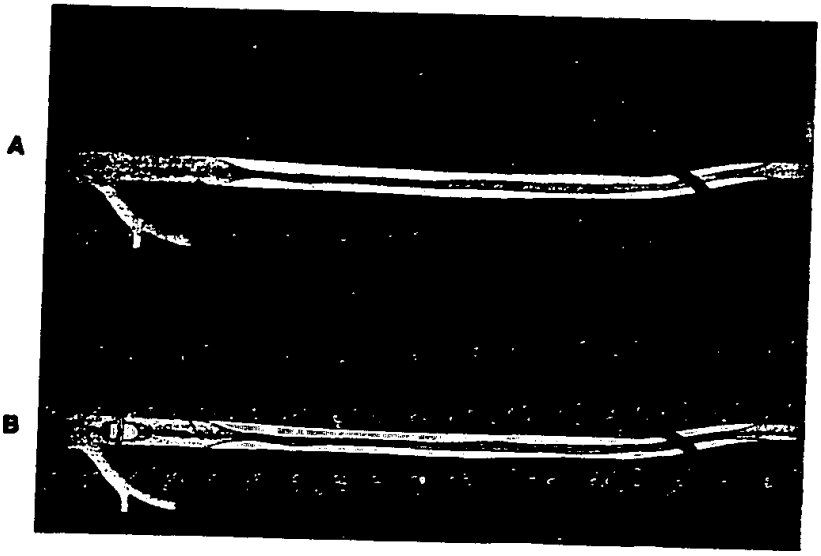

Fig. 2. A, Arteriotomy of the superficial femoral artery. **B,** Insertion of an introducer sheath and passage of the guidewire across the lesion distally.

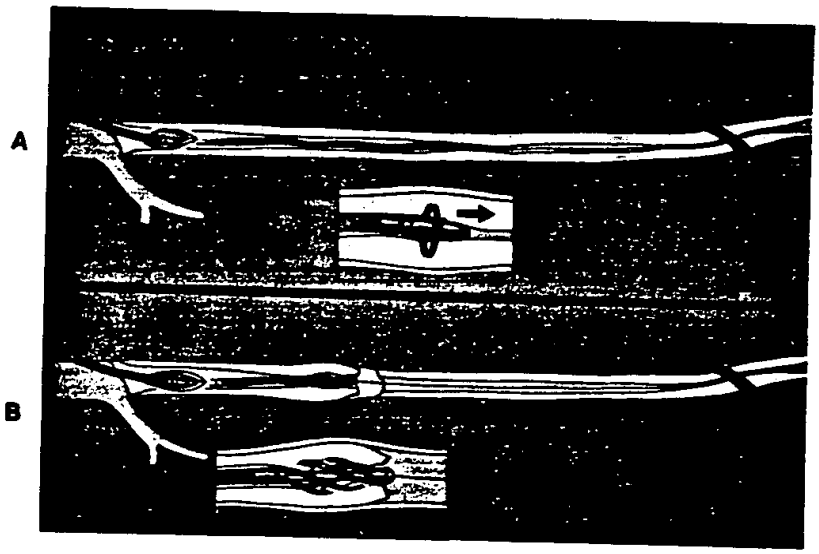

Fig. 3. A, Mechanical dilatation of the diseased superficial femoral artery using the Dynamic Dilator. **B,** Semiclosed endarterectomy using the Endarterectomy Catheter to engage the atheroma.

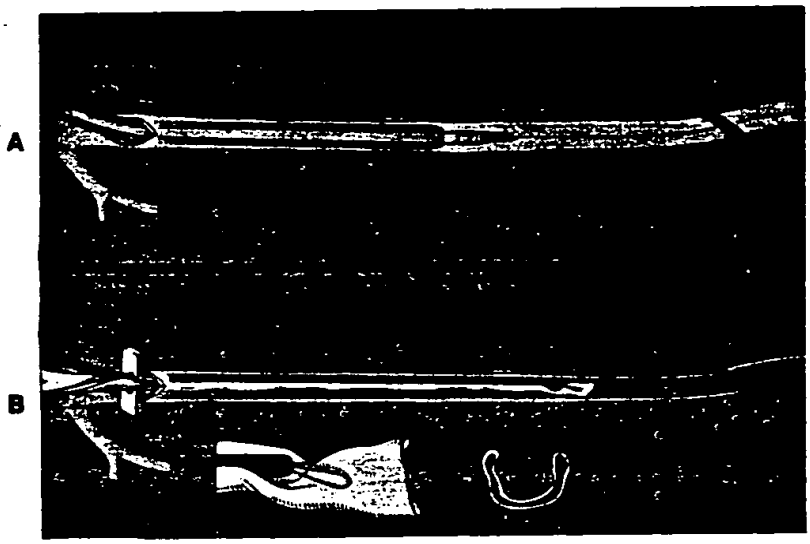

Fig. 4. A, Placement of an 18 F peel-away introducer sheath. **B,** Placement of the graft through the introducer sheath and into the femoropopliteal position using the Graft Inserter. The Graft Inserter pinches the graft near the distal end and lays over the folded graft.

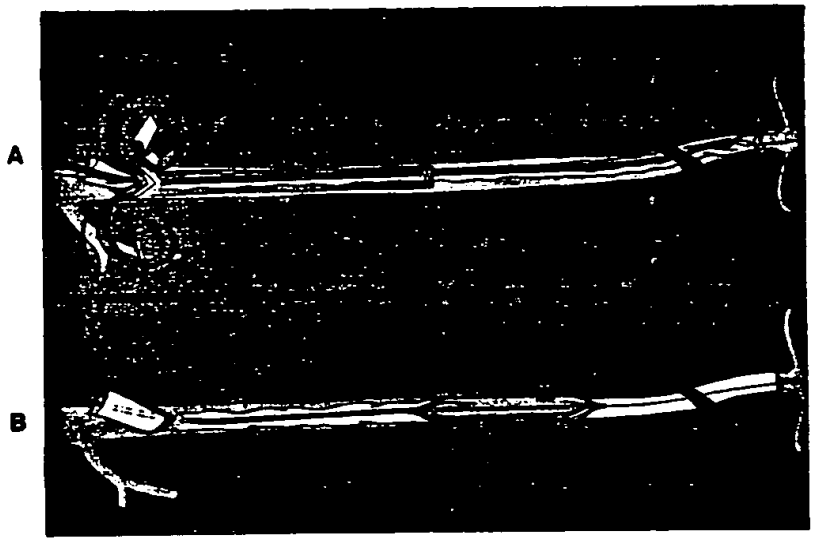

Fig. 5. A, Removal of the peel-away sheath while holding the PTFE graft in place with the Graft Inserter. **B,** Balloon dilatation of the graft.

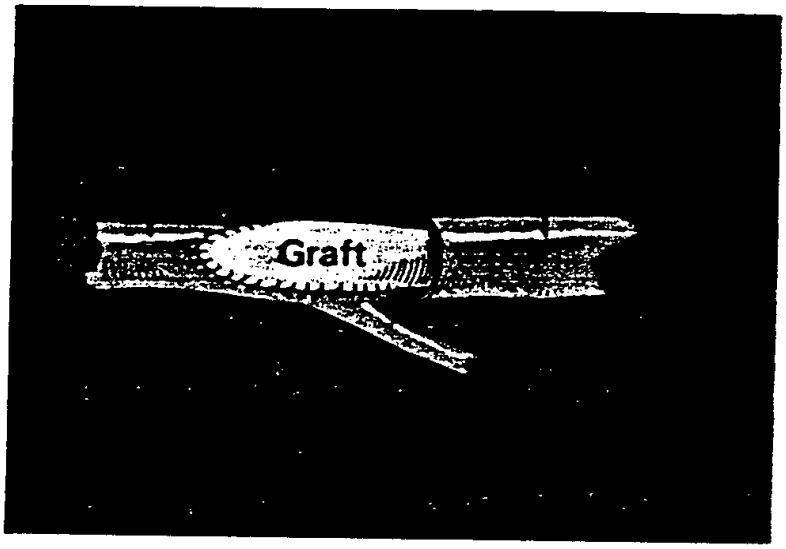

Fig. 6. Completion of standard end-to-end anastomosis of the proximal graft to the common femoral artery.

11. Standard end-to-end anastomosis of the proximal graft to the common femoral artery (Fig. 6)

Intraoperative arteriography was performed after steps 3, 5, 10, and 11. After the procedure was completed, the femoral and popliteal vessels were harvested and examined grossly for any technical defects. Furthermore, the harvested superficial femoral artery and the endarterectomy plaque were sent to the pathology laboratory for histologic examination. Histologic studies consisted of hematoxylin-eosin staining and microscopic evaluation. The procedures were performed at the UCLA Center for the Health Sciences Animal Research Center. Fluoroscopic road mapping guidance for the procedures was obtained with an Advantex CFM (General Electric Motors, Detroit, Mich.).

Animal Studies

After establishing the above procedural steps, we proceeded to the animal studies. With the approval of the institutional review board, we obtained six adult male mongrel dogs of Greyhound or Labrador descent that weighed 32 to 86 kg (mean 49 kg). These animals underwent unilateral endovascular femoropopliteal bypass using the same system and procedural steps as described above, except that the Dynamic Dilator and Endarterectomy Catheter were not used since the animals had normal vessels and no arteriosclerotic plaque. In addition, histologic studies were not performed in these animals. Each dog received a 10 cm length of 4.5 or 5.0 mm diameter, thin-walled PTFE graft.

All dogs received aspirin, 325 mg/day, pre- and postoperatively; and three dogs also received dipyridamole, 50 mg three times a day. All animals received intraoperative heparin, 100 units/kg, and heparin irrigation was used liberally. In addition, all animals received perioperative cefazolin. Papaverine was applied topically to the femoral artery on initial exposure. Arteriography was performed using Omnipaque contrast medium diluted 50% with saline solution. All animals underwent perioperative intravenous hydration to maintain an adequate urine output.

RESULTS

Human Cadaver Studies

The procedure was successfully completed in 10 of 13 human cadaver limbs. There were three failures: two due to inadequate instruments and one due to perforation of the artery. The average endarterectomy specimen length was 16 cm (range 1 to 38 cm). The average graft length inserted was 40 cm (range 30 to 45 cm). Average operative time was 1.6 hours (range 0.75 to 3.0 hours). Completion arteriography revealed a widely patent graft and a popliteal artery with a smooth distal artery-graft interface with no obvious defects in 9 of the 10 limbs in which the procedure was successfully completed (Fig. 7). One limb had a longitudinal fold at the distal interface due to a size mismatch between the artery and the graft (Fig. 8). Histologic studies of

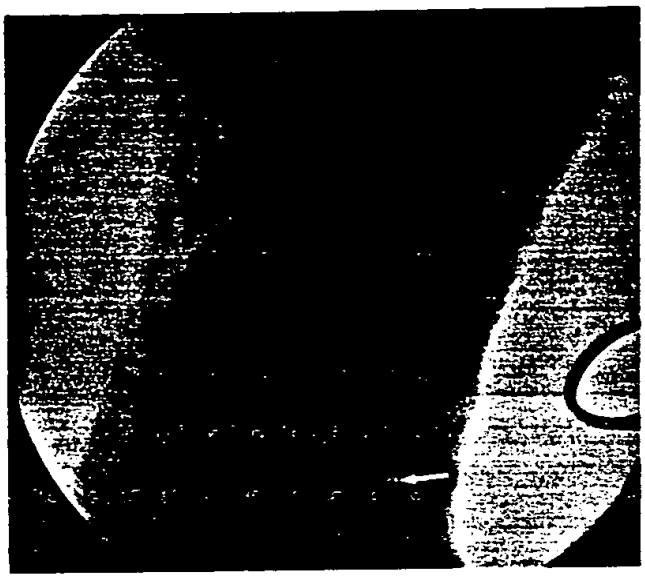

Fig. 7. Widely patent graft with no obvious defects in a human cadaver. Arrow points to the distal end point.

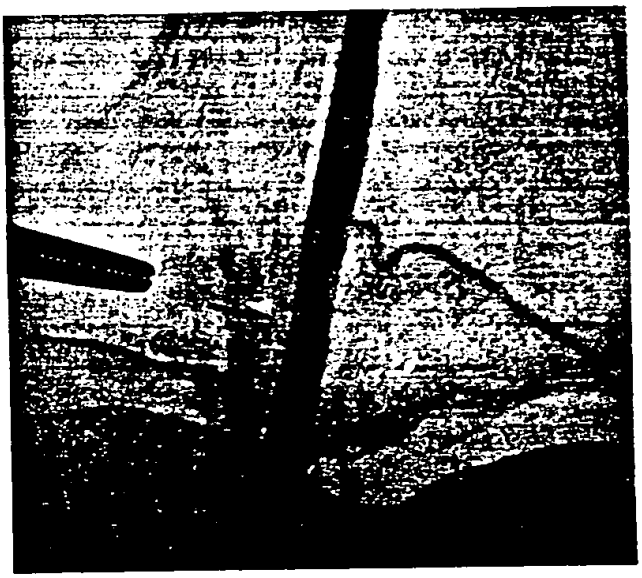

Fig. 8. Longitudinal fold at the distal interface due to a size mismatch of the artery and graft in a cadaver (arrow). (Femur is at the bottom of the illustration.)

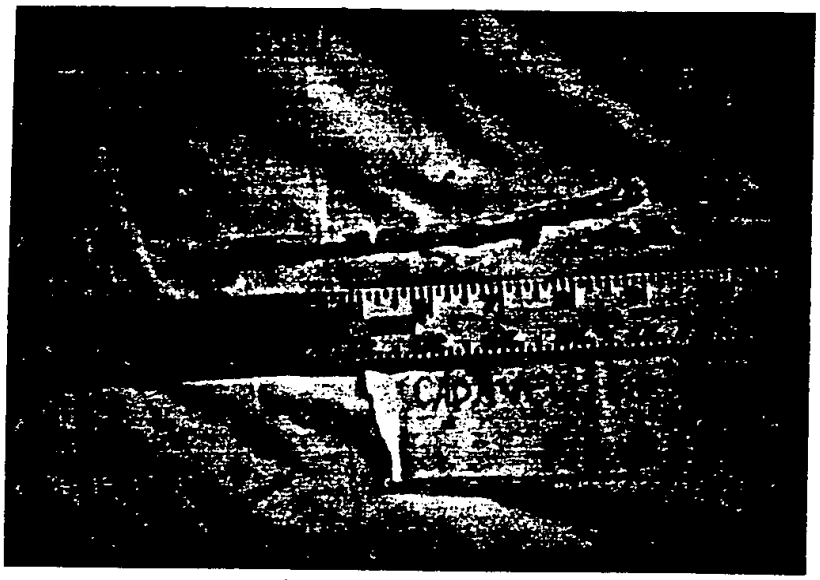

Fig. 9. Endarterectomized specimen revealing intima, atheromatous plaque, and media.

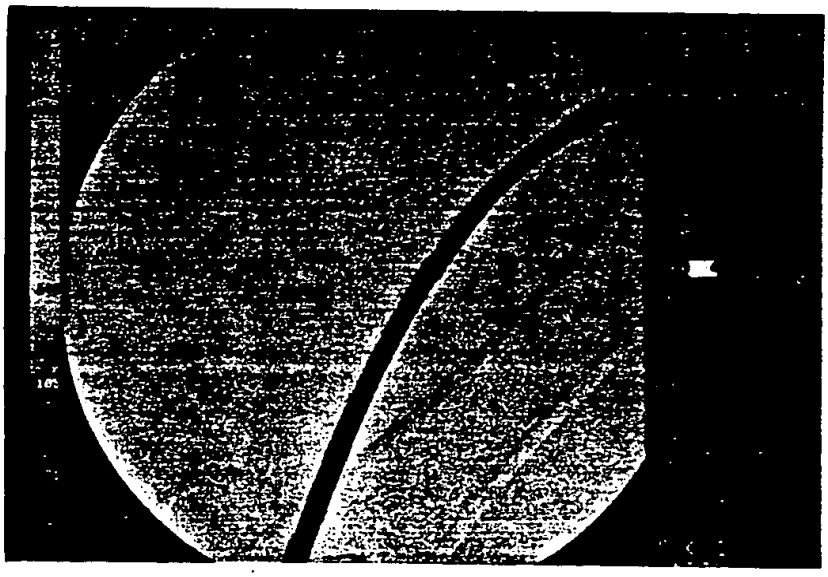

Fig. 10. Completion arteriogram revealing a patent graft in a dog. Arrow points to the distal end point.

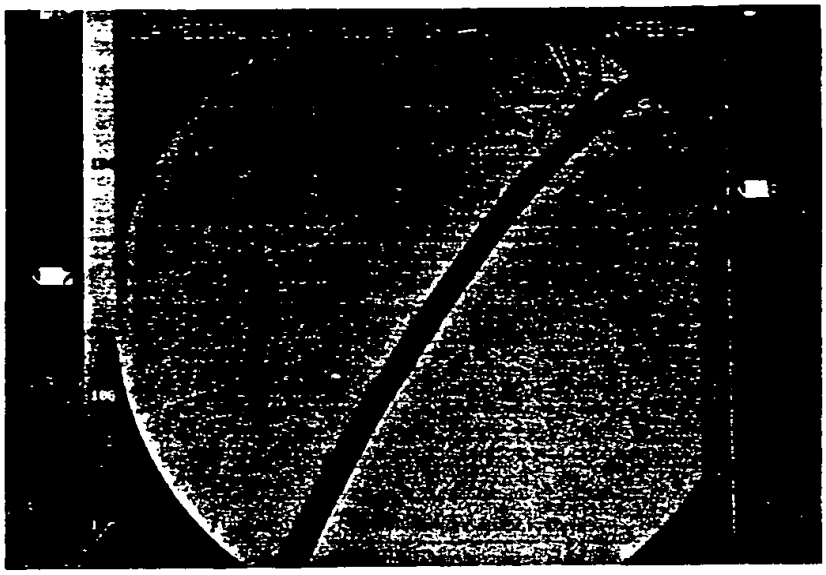

Fig. 11. Completion arteriogram revealing a longitudinal filling defect 1 cm from the distal end of the graft in a dog (arrow).

the superficial femoral artery revealed an intact outer media and adventitia. The endarterectomized specimen revealed intima, atheromatous plaque, and media (Fig. 9).

Canine Studies

We achieved technical success in all six dogs and arteriographic success in four of six (Fig. 10). In two dogs completion arteriography revealed a longitudinal filling defect 1 cm from the distal end of the graft where the Graft Inserter pinched the graft (Fig. 11). This fold at the previously pinched site was due to a size mismatch, that is, the artery was too small for the graft.

The average estimated blood loss was 792 ml (range 600 to 1000 ml) with the greatest blood loss occurring in the first two dogs. The average duration of the procedure was 2.9 hours (range 1.5 to 4.5 hours) with the longer durations occurring in the earlier treated dogs.

DISCUSSION

This limited study has demonstrated the technical feasibility of endovascular femoropopliteal bypass. Specifically, endoluminal semiclosed endarterectomy can be accomplished quite effectively using the Endarterectomy Catheter and the Dynamic Dilator. This method is effective for occlusive as well as stenotic lesions (Table I). Second, endoluminal graft placement is feasible using the above-described delivery system (Figs. 4, *A* and *B*, and 5, *A*). Finally, graft fixation can be achieved with a sutured anastomosis proximally and balloon dilatation distally (Figs. 5, *B*, and 6).

The idea of endovascular graft placement is not new. Its use had already been reported for aneurysmal disease.[7,8] Furthermore, Cragg and Dake[9] recently demonstrated the feasibility of percutaneous transluminal balloon dilatation followed by graft placement. In each of these studies stents played an integral role in fixing the graft in place and/or preventing arterial wall recoil.

The currently described method differs from those reported by previous investigators in several ways. First, stents are not used; avoidance of stent placement is desirable since stents are thrombogenic, easily compressible in the peripheral circulation, and expensive. Instead, sutures are used for the proximal attachment and simple balloon dilatation with an "elephant trunk" configuration is used for the distal fixation. To avoid arterial wall elastic recoil, an endarterectomy is performed prior to graft placement.

One might ask whether graft placement is needed after endarterectomy. Various investigators have reported long-term patency of endarterectomy similar to conventional prosthetic femoropopliteal bypass.[5,6] However, we feel that the endarterectomized arterial wall, being quite thin, will be prone to aneurysmal degeneration and/or perforation. Furthermore, the distal end point of an endarterectomy site may not be secure unless

it is covered by the graft. Finally, the graft itself may prevent intimal hyperplasia and restenosis by simple mechanical forces; fibroblasts and smooth muscle cells are known to exhibit contact inhibition.

The potential benefits of an endovascularly placed femoropopliteal graft are obvious. Its less invasive nature might allow this procedure to be performed on a 23-hour outpatient basis. The limited groin dissection, avoidance of a popliteal dissection, and elimination of an extravascular graft tunnel will result in less pain and leg swelling postoperatively. Theoretically the patency should be similar to that of a conventional femoropopliteal bypass, but the morbidity and the hospital cost would be less.

However, before this idea can be translated to broad clinical use, multiple problems still need to be resolved and/or avoided. The current study clearly shows the importance of a proper size match between the graft and the artery. Furthermore, the canine studies demonstrate that the backbleeding can be a significant problem and could lead to significant blood loss and/or thrombus formation at the distal interface during the time that the proximal anastomosis is performed. Finally, there is a theoretic possibility of retrograde blood flow and dissection between the distal graft and the artery, although previous studies of an endoluminal "elephant trunk" configuration in the thoracic aorta have not demonstrated this to be a problem,[10] and no retrograde dissection was demonstrated arteriographically in the cadavers or dogs. The issues will best be addressed by future clinical trials.

We conclude that endovascular femoropopliteal bypass through a single groin incision is technically feasible. Future studies are needed to test the efficacy, safety, and durability of this procedure. Work is currently in progress.

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